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By:

René Curry

PATENT

Customer No. 22,852

Attorney Docket No. 07579.0014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Andrew HEATON, et al.

Serial No.: 09/889,701

PCT Filed: February 15, 2000

National Stage Entry: November 5, 2001

For: Production of Isoflavone
Derivatives

) Group Art Unit: 1626

) Examiner: Golam M. Shameem

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JUN 28 2002

Commissioner for Patents and Trademarks
Washington, DC 20231

TECH CENTER 1600/2900

Sir:

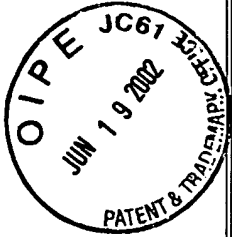
RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated February 19, 2002, the Office required restriction under 35 U.S.C. §§ 121 and 372. The Office notes a Lack of Unity requirement and alleges claims 1-46 are drawn to more than one inventive concept as defined by PCT Rule 13. Restriction is required according to the provisions of PCT Rule 13.2. Applicants are required, in response to this action, to elect between:

- I. Claims 1-9 and 40, drawn to a method of preparation of a compound of the formula II, classified in heterocyclic (549) class with plethora of subclasses.
- II. Claims 10-15 and 40, drawn to a method of preparation of a compound of the formula III, classified in heterocyclic (549) class with several subclasses.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com



- III. Claims 16-26 and 40, drawn to a method of preparation of a compound of the formula IV, classified in heterocyclic (549) class with several subclasses.
- IV. Claims 27-39 and 40, drawn to a method of preparation of a compound of the formula V, classified in heterocyclic (549) class with several subclasses.
- V. Claims 41-46, drawn to the compounds classified in (549) class with several subclasses.

Applicants provisionally elect to prosecute Group I, claims 1-9 and 40 drawn to a method of preparation of a compound of the formula II. However, Applicants traverse the Lack of Unity holding as improper, as set forth below.

The impropriety of the holding is highlighted by the prior treatment of the claims during the consideration of the PCT/AU00/00103 (Publication No. WO 00/49009). During its consideration, the International Searching Authority did not find that the original claims as filed lacked Unity of Invention. A copy of the International Search Report for PCT/AU00/00103 is filed concurrently herewith. While Applicants do not agree that any of the references are patent-defeating, these search results do show that the different methods and compounds could be searched together. Thus, the claims do not require the Office to perform any additional searches.

Additionally, Applicants specifically request that the claims of Group II (Claims 10-15 and 40, drawn to a method of preparation of a compound of the formula III, classified in heterocyclic (549) class with several subclasses) be considered with the claims of Group I for the following reason. PCT Rule 13.4 states, " Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention." Claims 10-15 are dependent

claims to the elected invention as described in claims 1-9 and would distinguish over the prior art for the same reasons as claims 1-9.

The Office states the application contains claims directed to more than one species of the generic invention. The Office requests Applicants to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

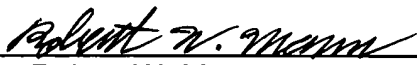
Applicants respectfully request clarification of the election of species requirement if different from the restriction requirement. It is not clear what the Office considers to be the generic invention or the species from which an election is to be made. The Office should identify distinct species of the claimed invention and specify the generic claims so that an informed decision can be made. MPEP 809.02(a).

In conclusion, Applicants provisionally elect with traverse to prosecute Group I. Applicants have extended the due date three months with the enclosed Petition for Extension of time and requisite fee. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 19, 2002

By: 
Robert W. Mann
Reg. No. 48,555

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 00/00103

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl⁷: C07D 311/36, 311/38, 311/04, 311/56

RECEIVED

According to International Patent Classification (IPC) or to both national classification and IPC

JUN 28 2002

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN: sub-structure search

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 80655/87 (606087) B (ZYMA S A) 5 May 1988	
X	Page 16, lines 4-8	1-9
X	Page 12, lines 13-19	16-17
X	Page 10, part (b)	27-28
X	Formula I, page 1 (relates to instant formula V), Formula II, page 10 (form I, IV), Formula III, page 10 (form III), Formula IIa, page 14 (form I), Formula IIc, page 16 (form II)	41-44

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 March 2000

Date of mailing of the international search report

24 MAR 2000

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200
WODEN ACT 2606 AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No.: (02) 6285 3929

Authorized officer

GAVIN THOMPSON

Telephone No.: (02) 6283 2240

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 00/00103

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Tetrahedron Letters, Volume 21, 1972 (UK), L Jurd et al, "Phenolic and Quinoidal Constituents of Dalbergia Retusa", pages 2149-2152	41-43
X	Formulas I and II (relates to instant formula I)	44
X	Formula I on page 2150, lines 3, 4 gives 7,8 Diacetoxy-4 ¹ -methoxyisoflavone (4H-1-Benzopyran-4-one, 7,8-bis (acetyloxy)-3-(4-methoxyphenyl)-) (see instant page 47, line 7)	
X	Journal of the Chemical Society 1957 (UK), W B Whalley, "5:4 ¹ -Dihydroxy-8-methyl isoflavone, and a Note on Lotoflavin" pages 1833-1837	
X	Formulas I and II (relates to instant formula I, IV). See page 1834, lines 7, 9, 27, 29, 30	41-43
X	Phytochemistry, Volume 28, No: 9, 1989 (UK), L V Alegrio et al, "Diarylheptanoids and Isoflavonoids from Centrolobium Species", pages 2359-2362	
X	Formulas IV-VII (relates to instant formulas V, I, IV, III, respectively). See page 2360	41-43
X	Patent Abstracts of Japan, JP 10-059956 A (KIKKOMAN CORPORATION) 3 March 1998	
X	See formula I (relates to instant formula I)	41-43
X	Patent Abstracts of Japan, JP 6-321752 A (KAO CORPORATION) 22 November 1994	
X	See formula (relates to instant formula I)	41-44
X	Patent Abstracts of Japan, JP 6-086682 A (KOBE STEEL LTD) 29 March 1994	
X	See 4 ¹ ,7,8-trihydroxyisoflavone (relates to instant formula I)	41-43
X	Patent Abstracts of Japan, JP 6-040876 A (KOBE STEEL LTD) 15 February 1994	
X	See 4 ¹ ,7,8-trihydroxyisoflavone (relates to instant formula I)	41-43
X	Patent Abstracts of Japan, JP 6-040909 A (KOBE STEEL LTD) 15 February 1994	
X	See 4 ¹ ,7,8-trihydroxyisoflavone (relates to instant formula I)	41-43
X	Patent Abstracts of Japan, C-79, page 743, JP 2-124883 A (THE KITASATO INSTITUTE) 14 May 1990	
X	See formula (relates to instant formulas I, IV and V)	41-44
X	Patent Abstracts of Japan, C-146, page 662, JP 1-226824 (OTA ISAN K K) 11 September 1989	
X	See formula I (relates to instant formula I)	41-44
X	Derwent Abstract Accession No: 27437 A/15, Class B02, D16, JP 50-160483 (MICROBIOCHEMICAL RE) 25 December 1975	
X	See formula I (relates to instant formula I)	41-44

INTERNATIONAL SEARCH REPORT

International application No.

PCT/ AU 00/00103

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Derwent Abstract Accession No: 02698 X/02, Class B02, JP 50-101360 (MICROBIAL CHEM RES INST) 11 August 1975 See formulas I and II (relates to instant formula I)	41-44
X	Derwent Abstract Accession No: 56352 W/34, Class B02, D16, JP 50-0035393 (MICROBIOCH RES FOUN) 4 April 1975 See formulas I to III (relates to instant formula IV)	41-44
Y	G P Ellis, "Chromenes, Chromanones and Chromones", published 1977 by John Wiley & Sons (New York) pages 256-260	16-26

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

DAVIES COLLISON CAVE
GPO Box 3876
SYDNEY NSW 2001

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3 JUL 2000

PROCESSED BY: m

ON 17/10/00

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing
(day/month/year) **16 OCT 2000**

Applicant's or agent's file reference
7464594/

DL to reply
16/10/00

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International application No.

PCT/AU00/00103

International filing date (day/month/year)

15 February 2000

Priority Date (day/month/year)

15 February 1999

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. ⁷ C07D 311/36, 311/38, 311/04, 311/56

Applicant

NOVOGEN RESEARCH PTY LTD et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- | | | |
|------|-------------------------------------|--|
| I | <input checked="" type="checkbox"/> | Basis of the opinion |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **15 June 2001**

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized Officer

GAVIN THOMPSON
Telephone No. (02) 6283 2240

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

WRITTEN OPINION

International application No.

PCT/AU00/00103

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 9 to 26, 31 to 39	YES
	Claims 1 to 8, 27 to 30, 40 to 44	NO
Inventive step (IS)	Claims 9 to 26, 31 to 39	YES
	Claims 1 to 8, 27 to 30, 40 to 44	NO
Industrial applicability (IA)	Claims 1 to 44	YES
	Claims	NO

2. Citations and explanations

NOVELTY (N) Claims 1 to 8

D1: AU 80655/87 (606087) B

The reduction of isoflavone (I) to form compounds of formula (II) by hydrogenation is anticipated by D1. See the reduction of isoflavone IIa to formula IIc on page 16 lines 1 to 8.

INVENTIVE STEP (IS) Claims 1 to 8

See above.

NOVELTY (N) ACKNOWLEDGED Claim 16

In D1, the reduction of isoflavone IIa to formula I is achieved by the Clemmensen reduction (which reduces the carbonyl to methylene (March, Jerry, "Advanced Organic Chemistry", third edition (1985), John Wiley, New York, page 1096)). This is irrelevant to the reaction of claim 16.

INVENTIVE STEP (IS) ACKNOWLEDGED Claim 16

See above.

NOVELTY (N) Claims 27 to 30

The reduction of compound (III) to form compound (V) is anticipated by D1. See the reduction of formula (III) to formula (I) on page 10 part (b) and page 16 process (b).

INVENTIVE STEP (IS) Claims 27 to 30

See above.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of VNOVELTY (N) Claims 40

Compounds of formulas (II) and (V) are prepared by processes in D1 that anticipate claims 1 and 27 respectively. See the previous page.

INVENTIVE STEP (IS) Claim 40

See above.

NOVELTY (N) Claims 41 to 44

D2: Tetrahedron Letters, Volume 21, 1972 (UK), L. Jurd et al, "Phenolic and Quinoidal Constituents of Dalbergia Retusa", pages 2149-2152

D3: Journal of the Chemistry Society 1957 (UK), W. B. Whalley, "5:4'-Dihydroxy-8-methylisoflavone, and a note on Lotoflavin", pages 1833-1837

D4: Phytochemistry, Volume 28, No. 9, 1989 (UK), L. V. Alegrio et al, "Diarylheptanoids and Isoflavonoids from Centrobium Species, pages 2359-2362

D5: Patent Abstracts of Japan, JP 10-059956 A (KIKKOMAN CORPORATION) 3 March 1998

D6: Patent Abstracts of Japan, JP 6-321752 A (KAO CORPORATION) 22 November 1992

D7: Patent Abstracts of Japan, JP-6-086682 A (KOBE STEEL LTD) 29 March 1994

8: Patent Abstracts Of Japan, JP 6-040876 A (KOBE STEEL LTD) 15 February 1994

D9: Patent Abstracts of Japan, JP 6-040909 A (KOBE STEEL LTD) 15 February 1994

D10: Patent Abstracts of Japan, C-79, page 743, JP 2-124883 (THE KITASATO INSTITUTE) 14 May 1990

D11: Patent Abstracts of Japan, C-146, page 662, JP 1-226824 (OTA ISAN K K) 11 September 1989

D12: Derwent Abstract Accession No. 27437 A/15, Class B02, D16, JP 50-160483 (MICROBIOCHEMICAL RE) 25 December 1975

D13: Derwent Abstract Accession No. 02698 X/02, Class B02, JP 50-101360 (MICROBIAL CHEM RES INST) 11 August 1975

D14: Derwent Abstract Accession No. 56352 W/34, Class B02, D16, JP 50-0035393 (MICROBIOCH RES FOUND) 4 April 1975

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

In D1, Formula I, page 1 corresponds to instant formula V; Formula II page 10, instant formulas I, IV; Formula III page 10, instant formula III; Formula IIa page 14, instant formula I; and Formula IIc page 16, instant formula II.

In D2, Formulas I and II correspond to instant formula I. 7,8-diacetoxy-4'-methoxyisoflavone (4H-1-Benzopyran-4-one-7,8-bis(acetyloxy)-3-(4-methoxyphenyl)) is not disclosed in D2.

In D3, Formulas I and IV corresponds to instant formulas I and IV respectively.

In D4, Formulas 4 to 7 corresponds to instant formulas V, I, IV and III respectively.

In D5, Formula given corresponds to instant formula I. Instant R₁ can be alkyl can be substituted by carboxyl and hydroxyl. See instant page 8 lines 23 to 27.

In D6, Formula given corresponds to instant formula I.

In D7 to D9, their 4',7,8-trihydroxyisoflavone is contained within the instant formula I.

In D10, Formula given corresponds to instant formulas I, IV and V.

In D11, Formula I corresponds to instant formula I.

In D12, Formula I corresponds to instant formula I.

In D13, Formulas I and II are contained within instant formula I.

In D14, Formulas I to III are contained within instant formula IV.

INVENTIVE STEP (IS) Claims 41 to 44

as above.